

**REMARKS**

This Application has been carefully reviewed in light of the *Office Action*. At the time of the *Office Action*, Claims 40-44, 46-57, 62-63, and 65-72 were pending and rejected. Applicants respectfully request reconsideration and favorable action in this case.

**Objections to Specification**

The Examiner objects to the specification under 35 U.S.C. § 132 as allegedly containing new matter. Specifically, the Examiner argues “[a]lthough applicant appears to have support for a constant thread height and pitch, applicant does not appear to have support for the term ‘substantially’ constant.” See *Office Action*, page 2, lines 9-11. Applicants respectfully traverse this objection.

According to the M.P.E.P., “[b]y disclosing in a patent application a device that inherently . . . has a property . . . a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.” § 2173.07(a).

Applicants respectfully contend one of ordinary skill in the art would appreciate Applicants’ specification supports substantially constant physical characteristics (e.g., thread pitch and the thread height) for example due to manufacturing imperfections or tolerances.

**Section 112 Rejections**

The Examiner rejects Claims 40-44, 46-57, 62-63, and 65-72 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully traverse those rejections for the reasons stated below.

With respect to Claims 40-44, 46-57, 62-63, and 65-72, the Examiner asserts “applicant does not have support for the term ‘substantially’ which broadens the dimensions to a range such that adjacent threads may have slightly different dimensions.” See *Office Action*, page 3, lines 3-5. However, According to the M.P.E.P., “[b]y disclosing in a patent application a device that inherently . . . has a property . . . a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.” § 2173.07(a).

Applicants respectfully contend one of ordinary skill in the art would appreciate Applicants' specification supports substantially constant physical characteristics (e.g., thread pitch and the thread height) for example due to manufacturing imperfections or tolerances. Consequently, Applicants respectfully request the Examiner to withdraw the associated rejections of Claims 40-44, 46-57, 62-63, and 65-72, under 35 U.S.C. § 112, first paragraph.

### **Section 102 Rejections**

The Examiner, under 35 U.S.C. § 102(b), rejects as allegedly being anticipated: Claims 40-42, 44, 47, 50, 52-57, 62, 63, 66, and 70-72 by U.S. Patent No. 5,951,560 to Simon et al. ("*Simon*"), Claims 40, 55, and 70-72 by U.S. Patent No. 3,726,180 to Rosan, Sr. ("*Rosan*"), Claims 40-44, 47, 50, 52-57, 62-63, 66, 70, and 72 by U.S. Patent Publication No. 2002/0038123 A1 by Visotsky et al. ("*Visotsky*"). The Examiner, under 35 U.S.C. § 102(e), further rejects Claims 40-42, 44, 50, 52-57, 63, 66, 70, and 72 as allegedly being anticipated by U.S. Patent No. 7,608,105 B2 to Pavlov ("*Pavlov*"). The Examiner, under 35 U.S.C. § 103(a), rejects Claims 67-69 as allegedly being unpatentable over *Visotsky*. Applicants respectfully traverse those rejections for the reasons stated below.

#### **I. Both *Simon* and *Rosan* fail to disclose a "substantially constant thread height" as recited in Claim 40.**

Claim 40 recites "at least one continuous and uninterrupted thread including a crest with a substantially flat surface and having a substantially constant thread height." The Examiner rejects those limitations by pointing to a medical implant illustrated in Figure 2 of *Simon* and arguing, "... fig. 2, is considered substantially constant, there is a small taper, but appears to be just as tapered or 'substantially constant' as applicants show their threads in fig. 1a, 1b of the present application." See *Office Action*, page 4, lines 1-3. Applicants respectfully disagree. The thread height of the alleged threads of *Simon* is not substantially constant. Rather, it is tapered.

*Simon* explains that "[t]he tapered form of the screws 10 and 30 facilitate an insertion thereof into the respective gaps G with a uniform turning force which remains fairly constant as the screw is inserted into the respective gaps G until the compression force begins to develop." *Simon*, col. 5, lines 21-25. That is, *Simon* teaches that the intended purpose of the tapered thread height is to "facilitate an insertion . . . with a **uniform turning force** which remains fairly constant . . . until the compression force begins to develop." *Id.* (emphasis

added). Consequently, one of ordinary skill in the art would not be motivated to modify the tapered thread height of *Simon* to be substantially constant because doing so would render the thread inoperable for its intended purpose of facilitating insertion with uniform turning force until compression begins to develop.

According to the MPEP, “[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. See §2143.01(V). Additionally, the examination guidelines issued by the United States Patent and Trademark Office (“PTO”) in response to the U.S. Supreme Court’s recent decision in *KSR Int’l Co. v. Teleflex, Inc* state, in part, that “[t]he rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods *with no change in their respective functions...*” *Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57526, 57529 (Oct. 10, 2007) (emphasis added). According to this standard, there is no motivation to modify the device of *Simon* to include anything other than a tapered thread height.

The Examiner also relies on Figure 1 of *Rosan* to reject the above-quoted limitations of Claim 40, arguing “(shown as constant height in fig. 1).” See *Office Action*, page 4, lines 21-22. However, Figure 1 of *Rosan* shows that the alleged thread is tapered in height. See e.g., Fig. 1, Taper A. As explained by *Rosan*:

A portion of thread convolutions 12 are **uniformly reduced in diameter** to provide forming threads 12a whereby the crests of thereof lie in a cylindrical plane passing through the crests of the other thread convolutions in an amount designate by Angle A”

*Rosan*, Col. 2, lines 4-9. That is, *Rosan* explicitly teaches that the intended purpose of the tapered thread height is to “provide forming threads 12a.” Consequently, one of ordinary skill in the art would not be motivated to modify the tapered thread height of *Rosan* to be substantially constant because doing so would render it inoperable for its intended purpose of providing the forming threads.

While the Examiner contends that Figures 1a and 1b of Applicants’ specification shows a substantially constant thread height, Applicants respectfully point out that that thread

height is tapered. As explained in Applicants' previous responses dated 04/28/2008 and 12/22/2008, Applicants' specification includes support for both tapered (see e.g., Figures 1a and 1b) and substantially constant (see e.g., originally filed claims) thread heights.

Since neither *Simon* nor *Rosan* disclose a "at least one continuous and uninterrupted thread . . . having a substantially constant thread height," and since one of ordinary skill in the art would not have been motivated to modify the tapered threading on the devices shown in either of those references, Applicants respectfully contend that Claim 40 and its dependent claims (e.g., Claims 41-43, 46-54, and 72) are allowable over *Simon* and *Rosan*. For analogous reasons, independent Claims 44, 55, and 70 and each of their respective dependent claims (e.g., Claims 56-57, 62-63, and 65-66 and Claim 71) are allowable over *Simon* and *Rosan*.

**II. Both *Pavlov* and *Visotsky* fail to disclose a "substantially constant thread height" as recited in Claim 40.**

Claim 40 recites "at least one continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end." The Examiner rejects those limitations by pointing to a medical implant illustrated in Figure 1 of *Pavlov* and arguing, "(plurality of individual threads, each one uninterrupted seen in fig. 1)." See *Office Action*, page 4, lines 10-11 (emphasis in original). However, the alleged thread of *Pavlov* is not uninterrupted. Rather, *Pavlov* explains that sections of the alleged thread are cut away:

These flutes are defined by the **sections 52 which are removed from the threads**. In a preferred embodiment, the flutes become narrower as they approach the proximal end 26 due to the fact that thread relief for purposes of self-tapping becomes less important as the cage reaches a final resting position.

*Pavlov*, Col. 3 line 65 - Col. 4, line 3. That is, *Pavlov* explicitly discloses that its alleged thread is interrupted by cut-away sections 52. Moreover, *Pavlov* explains that the intended purpose of the cut-away sections is to make the device "self-tapping." Consequently, one of ordinary skill in the art would not be motivated to modify the device of *Rosan* to include an uninterrupted thread because doing so would render the device inoperable for its intended purpose of being self-tapping.

The Examiner also relies on Figure 1 of *Visotsky* to reject the above-quoted limitations of Claim 40, arguing “(plurality of individual threads 41, each one being uninterrupted seen in fig. 1).” See *Office Action*, page 5, lines 7-9. However, Figure 1 of *Visotsky* shows that its alleged thread is interrupted by a slot 50. See e.g., Fig. 1, Slot 50. As explained by *Visotsky*:

**Slot 50 of implant 10 is formed transversely through the implant.**

Slot 50 can be filled with autogenous bone, allogenic bone, xenograft bone, demineralized bone, bone paste, cellular material, growth factors, and the like to stimulate healing and remodeling of the implant within the fracture site.

*Visotsky*, paragraph [0027] (emphasis added). That is, *Visotsky* explicitly discloses that its alleged thread is interrupted by slot 50. Moreover, one of ordinary skill in the art would not be motivated to remove slot 50 from the device of *Visotsky* because doing so would eliminate that device’s ability to be packed with biologic materials, rendering it inoperable for its intended purpose of stimulating healing and remodeling of the implant within the fracture site.

While the Examiner also seems to contend that the above-quoted limitations of Claim 40 are disclosed by a “plurality of threads,” “each one being uninterrupted;” see e.g., *Office Action*, page 5, lines 7-9, Applicants respectfully point out that none of those alleged threads spans “from the first end to the second end” as recited by Claim 40.

Since neither *Pavlov* nor *Visotsky* disclose “at least one continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end,” and since one of ordinary skill in the art would not have been motivated to modify the interrupted threading on the devices shown in either of those references, Applicants respectfully contend that Claim 40 and its dependent claims (e.g., Claims 41-43, 46-54, and 72) are allowable over *Pavlov* and *Visotsky*. For analogous reasons, independent Claims 44, 55, and 70 and each of their respective dependent claims (e.g., Claims 56-57, 62-63, and 65-66 and Claim 71) are allowable over *Pavlov* and *Visotsky*.

**Section 103 Rejections**

The Examiner, under 35 U.S.C. § 103(a), rejects as allegedly being unpatentable: Claims 67-69 over *Visotsky*. Applicants respectfully traverse this rejection for the reasons stated below.

As explained above with respect to the § 102(b) rejection of Claim 40 over *Visotsky*, *Visotsky* fails to disclose, “at least one continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end,” and one of ordinary skill in the art would not have been motivated to modify the device of *Visotsky* to overcome this deficiency. For at least those reasons, Applicants respectfully contend that Claim 67 and its dependent claims (e.g., Claims 68-69) are in condition for allowance.

**No Waiver**

Applicants have merely discussed example distinctions from the references cited by the Examiner. Other distinctions may exist, and Applicants reserve the right to discuss those additional distinctions in a later Response or on Appeal, if appropriate. By not responding to additional statements made by the Examiner, Applicants do not acquiesce to the Examiner's additional statements. The example distinctions discussed by Applicants are sufficient to overcome the Examiner's rejections.

**All Claims Are in Condition for Allowance**

For at least the reasons explained above, Applicants respectfully contend that each and every one of the claims of the instant Application are in condition for allowance. Applicants respectfully request allowance of all pending claims.

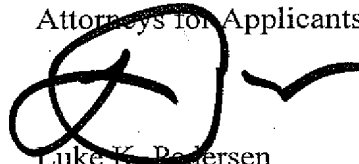
**CONCLUSION**

Applicants have made an earnest attempt to place this case in condition for allowance. For the foregoing reasons, and for other apparent reasons, Applicants respectfully request full allowance of all pending Claims. If the Examiner feels that a telephone conference or an interview would advance prosecution of this Application in any manner, the undersigned attorney for Applicants stand ready to conduct such a conference at the convenience of the Examiner.

Applicants believe no fee is due. However, if a fee is required, the Commissioner is hereby authorized to charge any fees or credit any overpayments to **Deposit Account No. 02-0384 of Baker Botts L.L.P.**

Respectfully submitted,

BAKER BOTTS L.L.P.  
Attorneys for Applicants

  
Luke K. Pedersen  
Reg. No. 45,003

Date: 1/4/10

**CORRESPONDENCE ADDRESS:**

Customer Number: **05073**